

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Fumitoshi Asai et al.
Serial No.: 10/600,266
Filed: June 20, 2003
For: Medicinal Compositions Containing Aspirin

Group Art Unit: 1614
Examiner: Kwon, Brian Yong S
Confirmation No. 7488

**PETITION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. § 1.705(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This letter is to request reconsideration of the patent term adjustment calculation indicated in the Notice of Allowance under Rule 705(b) for the captioned application.

On August 20, 2010, the USPTO mailed a Determination of Patent Term Adjustment under 35 U.S.C. §154(b) (Form PTOL-85) with the Notice of Allowance. According to the USPTO's Determination, the above-referenced application should be entitled to a period of 285 days of Patent Term Adjustment (PTA). This application is not subject to a terminal disclaimer.

Applicants for U.S. Patent Application Serial No. 10/600,266 ("the '266 application") respectfully request recalculation of the Determination of Patent Term Adjustment under 35 U.S.C. §154(b) (Form PTOL-85) mailed on August 20, 2010, for the reasons detailed herein. In particular, Applicants respectfully request recalculation of the period for Applicant delay under Rule 704 from 119 days to 95 days (or 89 days if submission of a supplemental paper after an RCE is not considered Applicant delay) and request that the final patent term adjustment for the '266 application include an additional period of 16 days for the number of days that exceed 36 months from the filing date of the application, to the issue date of the application, excluding the period following the filing of an RCE, for a total of 325 days (or 331 days if submission of a supplemental paper after an RCE is not considered Applicant delay), as shown below:

	<u>USPTO</u>	<u>Applicant</u>	
(minus)	A Delay:	404 days	
(plus)	Applicant Delay:	119 days	95 days (or 89 days*)
	B Delay	---	16 days
	Total:	285 days	325 days (or 331 days*)

*if submission of a supplemental paper after an RCE is not considered Applicant delay

For the reasons set forth below, patentee respectfully requests that the patent term adjustment be changed to at least 325 days (with the Applicants being entitled to an additional period for patent term adjustment if a patent issues from the '266 application more than 4 months after payment of the issue fee under 37 C.F.R. §1.703(a)(6)). The Commissioner is hereby authorized to charge the \$200 fee required by Rule 18(e) and any other fees which may be required for consideration of this paper to Deposit Account No. 50-3732, Order No. 17620.105003US2.

Calculation of Periods for Patent Term Adjustment

USPTO Delay Under 35 U.S.C. §154(b)(1)(A)(i)

Pursuant to 35 U.S.C. §154(b)(1)(A)(i), Applicants are entitled to patent term adjustment for failure by the USPTO to mail an action under 35 U.S.C. § 132 not later than 14 months from the date on which an application was filed under 35 U.S.C. § 111(a) ("14-month delay"). The '266 application was filed on June 20, 2003. The first office action by the USPTO for the '266 application was mailed on September 28, 2005. The USPTO calculated a period of 404 days for delay under §154(b)(1)(A)(i) for the period beginning August 20, 2004 (*i.e.*, 14 months from the June 20, 2003 filing of the application under 35 U.S.C. § 111(a)) until the mailing of the first office action on September 28, 2005.

Applicant Delay Under 35 U.S.C. §154(b)(2)(C)(ii)

According to 35 U.S.C. §154(b)(2)(C)(ii), the reduction in PTA is based on "any periods of time in excess of three-months that are taken to respond to a notice from the Office making any rejection, objection, argument or other request, measuring such three-month period from the date the notice was given or mailed to the applicant." The USPTO calculated a total of 119 days

of Applicant delay. Applicants respectfully submit that this calculation should be corrected to 95 days.

According to the USPTO's calculations, the PTA should be reduced by a period of 30 days for the time in excess of three-months Applicants took to file an RCE in response to the Final Office Action. A Final Office Action for the '266 application was mailed on March 6, 2006. A response to the Final Office Action was filed on May 5, 2006. The Examiner responded with an Advisory Action on May 26, 2006. A Request for Continuing Examination (RCE) was filed on July 6, 2006. The USPTO's calculations did not take into account that the Applicants had responded to the Final Office Action on May 26, 2006, within the three-month period permitted by 35 U.S.C. §154(b)(2)(C)(ii) and imposed a reduction of 30 days on the patent term adjustment for a portion of the time (the portion occurring more than three-months after mailing of the Final Office Action) that Applicants took after the Examiner had issued an Advisory Action. While the MPEP does not provide any specific guidance with respect to patent term adjustment calculations relating to Advisory Actions, the basis for this deduction in patent term adjustment appears to be based on a purported requirement for Applicants to comply fully with 37 C.F.R. § 1.113(c) to be deemed to have replied to a Final Office Action. Rule 113(c) states that a "[r]eply to a final rejection or action must include cancellation of, or appeal from the rejection of, each rejected claim." 37 C.F.R. § 1.113(c). Thus, the USPTO appears to take the position that a reply to a Final Office Action, for patent term adjustment calculation purposes, remains outstanding until cancellation or appeal of each rejected claim.

Applicants respectfully submit that Rule 1.113(c) is not applicable to calculating Applicant delay under 37 C.F.R. § 1.704(b). Rule 1.704(b) specifically applies to a period for Patent Term Adjustment based on the amount of time taken "to reply to any notice or action by the Office making any rejection, objection, argument or other request." (*emphasis added*). Rule 1.704(b) does not require that such a reply meet the standards of Rule 1.113(c). Rather, for the purpose of PTA calculations, Rule 1.704(b) explicitly states that "[t]he period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph." As detailed below, Applicants respectfully submit that the May 6, 2006 response was filed within the three-month period permitted under the 35 U.S.C. §154(b)(2)(C)(ii) and that the mailing of an Advisory Action triggered a second three-month period, which expired after the RCE was filed.

Applicant submitted a reply on May 6, 2006 to the March 6, 2006 Final Office Action. This reply was timely filed within the three-month period permitted under 35 U.S.C. §154(b)(2)(C)(ii). The MPEP and communications from the USPTO for the '266 application refer to the paper submitted on May 26, 2007 as a "reply" to the Final Office Action. For example, MPEP §706.07(f) provides that an Examiner is required to provide an Advisory Action "if the reply is filed within 2 months of the date of the final Office action." MPEP §714.13 also provides that an Advisory Action "should be used to acknowledge receipt of a reply from applicant after final rejection where such reply is prior to filing of an appeal brief and does not place the application in condition for allowance." In addition, the Advisory Action of May 26, 2006 refers to the paper submitted on May 6, 2006 as a "reply." Accordingly, Applicants respectfully submit that the papers submitted on May 6, 2006 fulfilled the requirements for a reply to an action by the USPTO under Rule 1.704(b) within the requisite three-month period and thus, does not incur any Applicant delay.

A second three-month period for Applicants to submit a reply was triggered by the Advisory Action dated May 26, 2006, which expired after the RCE was filed. The Advisory Action of May 26, 2006 maintained the earlier rejections and provided arguments in response to Applicants' submission of May 6, 2006. Accordingly, the Advisory Action is within the scope of an "action by the Office making any rejection, objection, argument or other request" as defined in Rule 1.704(b) and, therefore, triggers a second three-month period for Applicants to respond for the purpose of patent term adjustment calculations. Although the RCE was filed with an extension of time, Rule 1.704(b) clearly states that the period for reply set in the Office Action has no effect on the three-month period for the purpose of PTA calculations. Accordingly, Applicants acted promptly within the three-month periods permitted by 35 U.S.C. § 154(b)(2)(C)(ii) and no deduction of 30 days of patent term adjustment should be made for the period between the Final Office Action of March 6, 2006 and the filing of a Request for Continuing Examination on July 6, 2006.

Additionally, a second Final Office Action for the '266 application was mailed on November 5, 2008. Applicants filed a Notice of Appeal on May 5, 2009. According to the patent term adjustment calculations provided in the Notice of Allowance of August 20, 2010 and electronically on PAIR, the USPTO determined a period of 89 days of Applicant delay for the

time in excess of three-months Applicants took to file a Notice of Appeal in response to the Final Office Action.

According to 37 CFR §1.704(c)(8), there is a deduction in PTA for “[s]ubmissions of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment ... shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.” A response with a declaration signed by one of the inventors but not the others was filed with an RCE on October 16, 2007. As a supplement to the response of October 16, 2007, a substantially similar declaration signed by the other inventors was submitted to the USPTO on October 22, 2007. Applicants bring to the USPTO’s attention that the patent term adjustment calculations provided in the Notice of Allowance of August 20, 2010 and electronically on PAIR do not appear to impose a reduction of the patent term adjustment for the period between October 16, 2007 (the date the RCE was filed) to October 22, 2007 (the date a supplement to the response of October 16, 2007 was filed).

In sum, the total number of days attributable to Applicant delay should be the days in excess of three-months Applicants took to file a Notice of Appeal in response to the Final Office Action of November 5, 2008, which is 89 days. If the 6 day period between the filing of an RCE and submission of a supplemental paper is considered as additional Applicant delay, which the USPTO has not (as indicated by the calculation provided by the Notice of Allowance and electronically on PAIR), the total number of days attributable to Applicant delay would be increased by a period of 6 days (i.e., the period from October 16, 2007 to October 22, 2007), i.e., 89 days + 6 days, which is 95 days.

USPTO Delay Under 35 U.S.C. §154(b)(1)(B)

The calculations provided with the Notice of Allowance do not take into account any USPTO delay under 35 U.S.C. §154(b)(1)(B) for failure of the USPTO to issue a patent within 3 years after the actual filing date of the application (“B delay”). The period of B delay does not include any time after the submission of an RCE. The ‘266 application was filed on June 20, 2003 and an RCE was filed on July 6, 2007. Therefore, Applicants respectfully submit that

properly taking into account the B delay adds an additional 16 days (*i.e.*, the period from June 20, 2006 to July 6, 2007) of patent term adjustment.

Summary of Requested Correction to PTA

Applicants respectfully submit that the patent term adjustment for the '266 application should be the sum of the days of the 14-month delay and the B delay, *i.e.*, 404 days + 16 days, which is 420 days, minus period of Applicant delay, which accounts for 89 days, which in this case is 331 days.

If the period of time between the filing of an RCE on October 16, 2007 and the filing of a supplement on October 22, 2007 is attributable to Applicant delay, then the total patent term adjustment for the '266 application should be the sum of the days of the 14-month delay and the B delay, *i.e.*, 404 days + 16 days, which is 420 days, minus the total number of days for Applicant delay, which accounts for 95 days, which in this case is 325 days.

AUTHORIZATION

The Commissioner is hereby authorized to charge the fee set forth in 37 C.F.R. § 1.18(e) to Deposit Account No. **50-3732**, Order No. 17620-105003. The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this communication to Deposit Account No. **50-3732**, Order No. 17620-105003. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 17620-105003.

Respectfully submitted,
King & Spalding, LLP

Dated: November 19, 2010

By: 
Margaret B. Brivanlou / Wan Chich Lee
Reg. No. 40,922 / Reg. No. 57,297

Customer Number 65989
Correspondence Address:
King & Spalding
1185 Avenue of the Americas
New York, NY 10036-4003
(212) 556-2100 Telephone
(212) 556-2222 Facsimile